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CIVIL COVER SHEET

JS 44 (flev. 12/07) ne IS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating e civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.) DEFENDANTS **PLAINTIFFS** Eli Lilly & Company inited States of America, Ex Rel. John Doe County of Residence of First Listed Defendant Marion County (b) County of Residence of First Listed Plaintiff (IN U.S. PLAINTIFF CASES ONLY) (EXCEPT IN U.S. PLAINTIFF CASES) IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED. Attorneys (If Known) (c) Attorney's (Firm Name, Address, and Telephone Number) lichael M. Mustokoff Juane Morris LLP 0 South 17th Street hiladelphia, PA 19103-4196 hone: 215.979.1810 III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff I. BASIS OF JURISDICTION (Place an "X" in One Box Only) (For Diversity Cases Only) and One Box for Defendant) PTF DEF PTF □ 4 □ 4 Incorporated or Principal Place Citizen of This State 3 Federal Question ₫1 U.S. Government of Business In This State (U.S. Government Not a Party) Plaintiff **5** □ 5 2 Incorporated and Principal Place  $\square$  2 Citizen of Another State 4 Diversity ] 2 U.S. Government of Business In Another State (Indicate Citizenship of Parties in Item III) Defendant Citizen or Subject of a **3** 3 Foreign Nation Foreign Country V. NATURE OF SUIT (Place an "X" in One Box Only) OTHER STATUTES FORFEITURE/PENALTY BANKRUPTCY CONTRACT 400 State Reapportionment 422 Appeal 28 USC 158 610 Agriculture PERSONAL INJURY PERSONAL INJURY 110 Insurance 410 Antitrust 423 Withdrawal 620 Other Food & Drug 362 Personal Injury 310 Airplane 120 Marine 430 Banks and Banking 625 Drug Related Seizure 28 USC 157 Med. Malpractice 315 Airplane Product 130 Miller Act of Property 21 USC 881 450 Commerce 365 Personal Injury -140 Negotiable Instrument Liability 460 Deportation 630 Liquor Laws PROPERTY RIGHTS **Product Liability** 150 Recovery of Overpayment 320 Assault, Libel & 470 Racketeer Influenced and 640 R.R. & Truck 368 Asbestos Personal & Enforcement of Judgment Slander 820 Copyrights Corrupt Organizations 650 Airline Regs. Injury Product 330 Federal Employers 151 Medicare Act 830 Patent 480 Consumer Credit 660 Occupational 152 Recovery of Defaulted Liability 840 Trademark Liability 490 Cable/Sat TV Safety/Health PERSONAL PROPERTY 340 Marino Student Loans 810 Selective Service 690 Other 345 Marine Product (Excl. Veterans) 370 Other Fraud 850 Securities/Commodities/ [] 153 Recovery of Overpayment SOCIAL SECURITY Liability 371 Truth in Lending LABOR Exchange of Veteran's Benefits 350 Motor Vehicle 380 Other Personal 875 Customer Challenge 861 HIA (1395ff) 710 Fair Labor Standards 160 Stockholders' Suits 355 Motor Vehicle Property Damage 12 USC 3410 862 Black Lung (923) 863 DIWC/DIWW (405(g)) Act 890 Other Statutory Actions 385 Property Damage Product Liability 190 Other Contract Product Liability 720 Labor/Mgmt, Relations 195 Contract Product Liability 360 Other Personal Injury 391 Agricultural Acts 864 SSID Title XVI 730 Labor/Mgmt.Reporting 196 Franchise 892 Economic Stabilization Act 865 RSI (405(g)) & Disclosure Act PRISONER PETITIONS CIVIL RIGHTS REAL PROPERTY 893 Environmental Matters 740 Railway Labor Act 894 Energy Allocation Act 510 Motions to Vacate 441 Voting 790 Other Labor Litigation 210 Land Condemnation 895 Freedom of Information FEDERAL TAX SUITS Sentence 791 Empl. Ret. Inc. 442 Employment 220 Foreclosure Act Habeas Corpus: 230 Rent Lease & Ejectment 443 Housing/ Security Act 870 Taxes (U.S. Plaintiff 900Appeal of Fee Determination Accommodations 530 General 240 Torts to Land or Defendant) Under Equal Access 535 Death Penalty Welfare 245 Tort Product Liability 871 IRS—Third Party to Justice 445 Amer, w/Disabilities 540 Mandamus & Other **IMMIGRATION** 290 All Other Real Property 26 USC 7609 950 Constitutionality of 550 Civil Rights Employment 462 Naturalization Application State Statutes 446 Amer. w/Disabilities 555 Prison Condition 463 Habers Corpus -Other Alien Detaince 440 Other Civil Rights 465 Other Immigration Appeal to District Transferred from ORIGIN (Place an "X" in One Box Only) 7 Judge from 6 Multidistrict 4 Reinstated or 5 another district 3 Remanded from 1 Original 2 Removed from 邈 Magistrate Litigation Appellate Court Reopened (specify) State Court Proceeding Judgment Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): False Claims Act, 31 U.S.C. § 3729 et. seq. I. CAUSE OF ACTION Brief description of cause: False Claims against the United States and the states named in the Complaint. CHECK YES only if demanded in complaint: CHECK IF THIS IS A CLASS ACTION **DEMAND \$** II. REOUESTED IN JURY DEMAND: Yes □ No UNDER F.R.C.P. 23 COMPLAINT: III. RELATED CASE(S) (See instructions): DOCKET NUMBER JUDGE IF ANY TE SIGNATURE OF ATTORNEY OF RECORD ay 1, 2009 R OFFICE USE ONLY MAG. JUDGE CEIPT# APPLYING IFP JUDGE AMOUNT American LegalNet, Inc.

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# MSG

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF LOUISIANA, **COMMONWEALTH OF** MASSACHUSETTS, STATE OF NEVADA, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF MICHIGAN, STATE OF MONTANA, STATE OF NEW HAMPSHIRE, STATE OF NEW MEXICO, STATE OF NEW YORK. STATE OF NEW JERSEY, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF WISCONSIN, EX **REL. JOHN DOE** 

Plaintiff,

v.

ELI LILLY & COMPANY Lilly Corporate Center Indianapolis, Indiana,

Defendant.

CIVIL ACTION NO 9 - 1863

FILED IN CAMERA AND UNDER SEAL

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE QUI TAM PROVISIONS OF THE FEDERAL FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

## I. JURISDICTION AND VENUE

- 1. This is an action to recover damages and civil penalties on behalf of the United States of America and several individual states arising from Defendant Eli Lilly & Company's ("Lilly") conduct in causing the filing of false claims to be presented under the Federal Medicare, Medicaid, and CHAMPUS Programs.
- 2. Medicare is a federally funded health insurance program primarily for the elderly. Medicaid is a state and federal assistance program to provide payment of medical expenses for low income patients. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") is a program of medical insurance benefits provided by the federal government to individuals with family affiliations to the military services.
- 3. These qui tam claims arise under the provisions of the False Claims Act, 31 U.S.C. § 3729, et. seq. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 which specifically confer jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 & 3730.
- 4. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. § 3732(a) which provides: "any action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants any one defendant, can be found, resides, transacts business or in which any act proscribed by § 3729 occurred." Defendant Lilly transacts substantial business in the Eastern District of Pennsylvania.
- 5. This Court also has supplemental jurisdiction over the claims brought pursuant to the California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, Virginia, Georgia, Indiana, Michigan, Montana, New Hampshire, New Mexico, New York, New Jersey, Oklahoma, Rhode Island and Wisconsin *qui*

tam statutes pursuant to 28 U.S.C. § 1367 which provides that "in any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

6. Under the False Claims Act, this Complaint is to be filed *in camera* and remain under seal for a period of at least 60 days and shall not be served on the defendant until the Court so orders. The government may elect to intervene and proceed with the action within 60 days after it receives both the Complaint and the material evidence and information.

## II. PARTIES

- 7. Qui tam Plaintiff John Doe ("Relator") is a citizen and resident of the state of California. The Relator brings this action on behalf of the United States of America.
- 8. Simultaneously with the filing of this Complaint, Relator has filed a Motion for Leave to Proceed Under a Fictitious Name.
  - 9. The Relator is a present employee of Eli Lilly.

#### REDACTED

10. Simultaneously with the filing of this Complaint as required under the False Claims Act, the Relator has provided to the Attorney General of the United States, the United States Attorney for the Eastern District of Pennsylvania and the State Attorneys General identified in this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement supports the existence of false claims by Lilly in the Medicare, Medicaid and CHAMPUS Programs.

11. Defendant Lilly is a corporation incorporated under the laws of Indiana, with its principal place of business in Indianapolis, Indiana.

## III. FACTUAL ALLEGATIONS

- A. <u>Lilly's History of Engaging in the Illegal Practice of Off-label Marketing of its Pharmaceutical Products</u>
- 12. Off-label marketing is a practice whereby a pharmaceutical company promotes a drug for the treatment of symptoms and conditions other than those in its Federal Drug Agency ("FDA") approved indication.
- 13. A drug achieves an approved indication only after vigorous FDA review of tests and studies demonstrating the drug's safety and efficacy at a particular dosage. Restrictions can also be placed on patient populations so that the use is limited to those for whom the drug is considered both safe and effective.
- 14. Since 1999 and up to January 2009, Lilly has actively engaged in the practice of off-label marketing, often heedless of FDA indications.
- 15. In February, 2006, Lilly pled guilty to the crime of misbranding, 21 U.S.C. §§ 331(a), 333(a)(1) and 352(f)(1) arising from its illegal off-label sales of the drug Evista. Lilly promoted Evista, an FDA approved drug only for osteoporosis, as a drug to be used for the prevention of breast cancer and reducing the risk of cardiovascular disease. Lilly paid the federal government \$36 million in criminal fines, penalties and civil settlement.
- 16. In January 2009, Lilly pled guilty again to the crime of misbranding. In that guilty plea, Lilly admitted that during the period from 1999 through December 31, 2005, Lilly promoted its drug Zyprexa, approved by the FDA only for the treatment of bipolar mania I and schizophrenia, as a drug to be used in the treatment of anxiety, depression, irritability and other mood disorders and conditions.

- 17. At the same time, Lilly settled federal and state claims of off-label marketing of Zyprexa and the federal crime of misbranding regarding Zyprexa for \$1.42 billion dollars.
  - B. <u>Lilly's Management Actively Promotes Off-label Marketing Through a</u>
    System of Incentive Bonuses and Sales Representative Evaluations
- 18. Each Lilly sales representative is evaluated on the basis of his/her ability to perform against a management assigned goal based upon a basket of drugs which management determines to be an actual or potential competitor of a Lilly drug.
- 19. Many of the drugs included in the competitor basket are FDA approved for symptoms or disorders different from the FDA approved indications for the Lilly drug.
- 20. Members of the Lilly neuroscience sales group selling Zyprexa and Symbyax, (each an atypical antipsychotic), were evaluated against a basket of competitor drugs that included not only other atypical antipsychotics, but also various mood stabilizers and similar drugs which were FDA approved for symptoms and mood disorders, that were not FDA approved, for Zyprexa and Symbyax. (See chart attached as Exhibit "A").
- 21. Cymbalta is FDA approved for: Diabetic Peripheral Neuropathic Pain ("DPNP"), major depression disorder ("MDD"), general anxiety disorder ("GAD") and fibromyalgia.

  Nevertheless, members of the Lilly neuroscience group selling Cymbalta were evaluated against a basket of drugs approved by the FDA for the general treatment of pain and other off-label indications. Members of the Lilly Osteoporosis group were directed to sell Cymbalta symptom based for the treatment of pain. Members of the Lilly Cardiovascular group were directed to sell Cymbalta symptom based for the treatment of depression.
- 22. Strattera is FDA approved only for attention deficit hyperactivity disorder ("ADHD"). Members of the Lilly sales force were instructed and encouraged to market Strattera to physicians to treat those individuals "vulnerable" to certain symptoms associated with ADHD,

such as inattention and impulsivity. Because Strattera is not FDA approved for individuals vulnerable to symptoms associated with ADHD, such marketing practices amount to off-label marketing.

23. Members of the sales force were also encouraged to suggest the use of Strattera in combination with other stimulants outside any approved FDA indication. The sales force was also told to reference a medical letter regarding a combination of Strattera with other stimulants to give credence to their sales efforts.

## C. Off-label Promotion of Zyprexa since January 1, 2006.

- 24. Zyprexa continues to be approved by the FDA for the indications limited to schizophrenia and bipolar I mania. Neither of these indications is normally seen by primary care physicians who usually refer such patients to psychiatrists whose training and experience are considered necessary for the responsible treatment of these conditions.
  - 25. Zyprexa is not approved for the treatment of children under 18 or the elderly.
- 26. Despite having knowledge of the federal investigation of its off-label marketing activity as to Zyprexa as early as May, 2004, Lilly's sales force continued to promote and were encouraged by Lilly to promote the symptom based off-label sale of that drug to primary care physicians and child psychiatrists.
- 27. In January 2006, a primary care sales force unit was set up in the neuroscience sales division. Sales representatives focused attention on primary care physicians treating patients in nursing homes with dementia and other related problems and primary care doctors treating resistant depression. Zyprexa is not FDA approved for either dementia or resistant depression.
- 28. Included in Lilly's competitor basket for Zyprexa is the drug, Depakote, used in the treatment of seizures, bipolarity, migraines, each a condition for which Zyprexa is clearly not

FDA approved. Migraines and seizures are conditions routinely treated by primary care physicians.

- 29. Also included in the Zyprexa competitor drug basket is Lilly's drug Symbyax, which is indicated for bipolar depression.
- 30. Symbyax was approved for the treatment of bipolar depression in December, 2003.
- 31. The inclusion of Symbyax and Zyprexa in the <u>same</u> basket of competitors, despite the difference in the indications for the two drugs, evidences Lilly's intention to disregard those differences in its marketing of the two drugs.
- 32. Despite having knowledge of the federal investigation of its off-label marketing of Zyprexa to primary care physicians and child psychiatrists as early as May, 2004, Lilly's management continued to impose the very same competitive basket sales quotas and expectations on its sales representatives regarding Zyprexa, requiring and resulting in the off-label marketing and resulting sales of that drug.
- 33. Promotions, sales bonuses and evaluations continued to be based upon the very same measurements achieved through previous off-label marketing results. Sales representatives were required/expected to see the very same primary care physicians and child psychiatrists with whom they had always off-label marketed Zyprexa, requiring and resulting in the off-label sales of that drug.
- 34. Lilly manufactures Zyprexa in a sub lingual form called Zydis. Despite the same FDA limited approved indications, Zydis is marketed off-label principally to primary care physicians and psychiatrists treating elderly patients resistant to swallowing pills.

- 35. Neither Zyprexa nor Zydis has been indicated for treatment of the elderly for bipolar mania.
- 36. Despite its knowledge of the investigation in 2004, Lilly nonetheless continued to advocate and encourage off-label marketing of Zyprexa up to the finalization of its January 2009 civil and criminal settlement with the government. That settlement however only covered the period up through December 31, 2005. In January 2009, just as settlement of the government's misbranding and off-label marketing claims for Zyprexa were about to be made public, Lilly's management gave its first direction to the sales force to cease selling Zyprexa off-label as a general "bipolar" drug. FDA's approved indication is only for bipolar I mania.
  - 37. Attached as Exhibit "B" to this Complaint is just such a direction.

And the reason I say that is we now have to say bipolar I in our targeted patient when we talk about that. Before, we were allowed to say bipolar; now its bipolar I and I think the one we are going to do for the management team may be the one you want to roll out because primary care doctors may say "well, what's the difference between I? and II" and I think it's a good knowledge base for all of us to learn that. So, but that's your call if you want to roll out something different.

In the same conversation, the same supervisor states:

What you do with your own district is up to you, but I would recommend at least for Zyprexa to go through the bipolar I versus bipolar II, and the reason I say that is one of our number one missed areas, and, secondly, we now have to, in our patient setup, say bipolar I. Now we need to make sure everybody understands the difference between bipolar I, bipolar II, and some of the other, actually, things that can happen. In terms of the CIA corporate agreement that we are now having to comply with Zyprexa, Grady will be talking about that on stage, the first part of the general session."

38. The continuation of Lilly's Zyprexa primary care off-label marketing strategy is evidenced in its use of sample drugs provided to primary care physicians. The indicated <u>starting</u> dose for Zyprexa is 10 to 15 milligrams daily. Samples provided to the physicians, however,

were primarily 2.5 to 5 milligrams. The smaller dosage is used as an introduction to the off-label treatment of non-indicated symptoms such as depression and anxiety.

## D. Symbyax

- 39. Symbyax is a Lilly drug indicated only for bipolar depression.
- 40. Bipolar depression is a mental disorder treated by psychiatrists whose training and experience are considered necessary for the responsible diagnosis and treatment of these conditions.
- 41. Lilly's internal documents provided to its sales force regarding Symbyax state, "the brand strategy for Symbyax, with bipolar depression, remains focused on **expanding** use in the **primary care setting** and maintaining current prescribers in the psychiatry and account settings. Attached as Exhibit "C".
- 42. Symbyax and Zyprexa appear to be viewed as direct competitors as depicted in Lilly's competitive drug chart. (Exhibit "A") However, FDA approved indications for the two drugs are different. Moreover, neither drug is FDA approved for the same indications as Depakote, also included in the same competitive basket as Symbyax and Zyprexa. Depakote is indicated for bipolar disorder, as well as seizures and simple and complex migraines.
- 43. To further its expansively aggressive promotion to primary care physicians, Lilly retained a contract sales force, NovaQuest PCP specifically to focus promotion of Symbyax in the primary care setting.
- 44. Lilly's sales materials regarding, "customer targetings" [for primary care physicians] specifically state:

Target a group of ten Symbyax CATS [Customer Account Targets] target physicians that currently do not consider bipolar depression in their depressed patient population.

- 45. Lilly directed its sales personnel to instruct physicians as to what the <u>sales</u> representative considered to be a diagnosis of bipolar depression.
- 46. By giving such directions, Lilly engages in the off-label promotion of Symbyax to doctors not trained in the diagnosis of bipolar depression. In addition by equating Symbyax to non-Lilly drugs that have far broader FDA approved indications, Lilly is engaging in the off-label promotion of Symbyax.

## E. Cymbalta

- 47. Cymbalta is presently indicated for DPNP, MDD, GAD and fibromyalgia.
- 48. Lilly launched Cymbalta for the treatment of MDD in August, 2004.
- 49. Lilly launched Cymbalta for the treatment of DPNP in September, 2004.
- 50. Cymbalta was not approved for the treatment of fibromyalgia until June, 2008.
- 51. From its initial launch in 2004, Lilly's sales representatives promoted Cymbalta for the treatment of symptoms such as burning or chronic widespread pain, despite the absence of FDA approved fibromyalgia or chronic pain indications.
- 52. MDD and GAD appear in DSM-IV diagnostic criteria. They are serious mental diseases most commonly treated by psychiatrists.
- 53. DPNP is somatic pain often associated with diabetes and most commonly treated by endocrinologists.
- 54. Lilly sales personnel are currently promoting the off-label use of Cymbalta for treatment of general pain and depression. Lilly sales representatives are also promoting Cymbalta off-label to child psychiatrists. Cymbalta is not FDA approved for patients under the age of 18.

- 55. Included in Lilly's Cymbalta competitive basket are such drugs as Prozac, Zoloft, and Paxil, drugs indicated for social anxiety, panic, PTSD, conditions routinely treated by general practitioners.
- 56. Attached as Exhibit "D" is a page from a March, 2009 workbook provided to Lilly's sales force. It notes, "Key Changes to the Previous Sales Aid". It refers to data that has been removed from Sales Aid/IVA. [Interactive Visual Aid].
- 57. In April, 2009, Lilly issued a revised "Sales Director/Manager Facilitator's Guide, attached as Exhibit E.
- 58. The alleged purpose of this Guide was to state that "as a result of new data analysis, the focus of our promotion and core sales pieces have changed". Instead of promotion for painful somatic symptoms, the sales force was to sell Cymbalta for MDD and risk of relapse.
- 59. The actual reason for the revised sales pieces was to provide a reason to withdraw off-label marketing pieces that stressed, "vague aches; loss of interest; sadness and anxiousness", as opposed to Cymbalta's indications for MDD. See Exhibit "F" attached sales piece.
- 60. As stated in the Facilitator's Guide, the new IVA DOES NOT (emphasis in the original) have any of the painful physical symptom data.
- 61. As stated in the Facilitator's Guide, "The Cymbalta MDD promotional slide kits (core, emotional and painful physical symptoms) are no longer available for use".
- 62. As further evidence of Lilly's recognition of its prior off-label sales of Cymbalta for pain, it provided its sales force with an "Opening dialogue to share with customers".

  Attached as Exhibit "G". That document specifically instructs sales representatives to tell physician customers:

"You will see a change (emphasis added) in the patient type I will be describing today, as one of the areas under consideration

- revolves around Cymbalta's data in painful physical symptoms. While this process is occurring, I will be sharing data in a patient visit with major depression who is at risk of relapse."
- 63. Cymbalta has been openly marketed as a drug for mood disorder. The Prem1er Rewards program for fiscal 2009 states as a goal, "one combined market for Pain and Mood for all sales forces promoting Cymbalta." In its profile targeting primary care physicians, it describes such off-label symptoms as "aches and pains, loss of interest, sluggish."
- 64. The materials distributed by Lilly sales personnel up to April, 2009 promoted the use of Cymbalta in a variety of ways for which there was no supporting data. Lilly's sales aids had claimed, without substantiation, that, unlike Cymbalta, a competing group of antidepressant drugs failed to relieve somatic symptoms.
- 65. Lilly's off-label marketing of Cymbalta has been remarkably successful. On April 20, 2009, Lilly announced its first quarter sales results. It identified Cymbalta as its second highest selling drug after Zyprexa. Sales of Cymbalta were 17% higher in the first quarter of 2009 than they were in the previous year.
- 66. On information and belief, the removal of the illegal sales aids was prompted by the government's Corporate Integrity Agreement imposed on Lilly in January 2009. The off-label references to somatic symptoms and comparative statements in the absence of supporting data had been in use by Lilly during a period dating back to the introduction of Cymbalta in 2004.

#### F. Strattera

67. Strattera has been indicated for the treatment of ADHD since January, 2003.

Lilly's sales materials for Strattera make undocumented and unsupported claims as to Strattera's ability to prevent what Lilly associates as social consequences of ADHD such as divorce, job loss and even sexually transmitted diseases.

- directed to say that the drug is more effective than alternate stimulant treatments such as Ritalin.

  Lilly's sales materials direct its representatives to say, "the Strattera patient is the patient who is vulnerable to symptoms of ADHD, including impulsivity and inattention, in different settings throughout the day and evening." (See attached as Exhibit "H").
- 69. The FDA approved indications for Strattera do not include vulnerability to symptoms of ADHD. To the contrary, the FDA instructs:

A diagnosis of ADHD (DSM-IV) implies the presence of hyperactive – impulsive or inattentive symptoms that cause impairment that were present before age 7 years. The symptoms must be persistent, must be more severe than is typically observed in individuals at a comparable level of development, and must cause clinically significant impairment, e.g. in social, academic or occupational functioning, and must be present in two or more settings . . . the symptoms must not be better accounted for by another mental disorder. (Emphasis added).

### The FDA also instructs:

The specific etiology of ADHD is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but also of <u>special</u> psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the patient and not solely on the presence of their acquired number of DSM-IV characteristics.

## The FDA also notes:

"Drug treatment may not be indicative for all patients with ADHD. It is not intended for use in a patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis."

#### COUNT I.

## VIOLATION OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3729

- 70. Relator repeats and realleges paragraph 1-69 of this Complaint.
- 71. From at least January 1, 2006 continuing through January 15, 2009, (in the case of Zyprexa); from January, 2003 to April, 2009 (in the case of Strattera); from September, 2004 to

April, 2009 (in the case of Cymbalta); and from September, 2003 to the present (in the case of Symbyax), Lilly, in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 72. The United States, its fiscal intermediaries and state Medicaid programs, were unaware of Lilly's off-label sales promotion or the falsity of the records, statements and claims made by Lilly and as a result thereby have paid and continue to pay Medicare, Medicaid and CHAMPUS reimbursement that they would not otherwise have paid.
- 73. The United States has been damaged by the payment of false and fraudulent claims.
  - 74. WHEREFORE, Plaintiff demands judgment against Lilly as follows:
- a. that by reason of the aforementioned violations of the False Claims Act that this Court enter judgment in Plaintiff's favor and against Lilly in the amount equal to three times the amount of damages that the United States has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 nor more than \$10,000 for each violation of 31 U.S.C. § 3729;
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT II.

## VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT, CAL. GOV. CODE §12651

- 75. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 76. From at least January, 2003 continuing through April, 2009, Lilly, in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved the state of California in violation of CAL. GOV. CODE §12651(a)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 77. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta and Strattera causing to present to California's state funded Medicaid Health Program false or fraudulent claims for payment in violation of CAL GOV. CODE §12651(a)(1).
- 78. California's state Medicaid program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 79. The California State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of the California False
Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount
equal to not less than two times and not more than three times the amount of damages that

California has sustained because of Lilly's actions, plus a civil penalty of not more than \$10,000 for each violation of CAL. GOV. CODE §12651(a)(1);

- b. that Relator, as Qui Tam Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT III.

## VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. CODE ANN. TIT. 6 §1201

- 80. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 81. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Delaware in violation of DEL. CODE ANN. TIT. 6, §1201(a)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 82. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta and Strattera causing to present to Delaware's state funded Medicaid health care program false or fraudulent claims for payment in violation of DEL. CODE ANN. TIT. 6, §1201(a)(1).

- 83. Delaware's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 84. The Delaware State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Delaware False
  Claims and Reporting Act that this Court enter judgment in Plaintiffs' favor and against Lilly in
  an amount equal to not less than two times and not more than three times the amount of damages
  that Delaware has sustained because of Lilly's actions, plus a civil penalty of not less than
  \$5,500 and not more than \$11,000 for each violation of DEL. CODE ANN. TIT. 6, §1201(a)(1);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to DEL. CODE ANN. tit. 6, §1205(a) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiffs and Relator have such other and further relief that this Court deems just and proper.

## COUNT IV.

## VIOLATION OF D.C. CODE ANN. §§2-308.13–.15

- 85. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 86. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed caused the

submission of false or fraudulent claims to be paid or approved by the District of Columbia in violation of D.C. CODE ANN. §2-308.14(a)(1) through the off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 87. From at least January, 2003 continuing through April,-2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to District of Columbia's state funded Medicaid health care program false or fraudulent claims for payment in violation of D.C. CODE ANN. §2-308.14(a)(1).
- 88. The District of Columbia's Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 89. The District of Columbia Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of the District of Columbia's false claim provisions that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of D.C. CODE ANN. §2-308.14(a)(1);

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to D.C. CODE ANN. §2-308.15(f)(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT V.

## VIOLATION OF THE FLORIDA FALSE CLAIMS ACT, FLA. STAT. ANN. §68.081-.090

- 90. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 91. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Florida in violation of FLA. STAT. ANN. §68.082(2)(a)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 92. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Florida's state funded Medicaid health care program false or fraudulent claims for payment in violation of FLA. STAT. ANN. §68.082(2)(a)(1).
- 93. Florida's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.

94. The Florida State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Florida False

  Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount
  equal to not less than two times and not more than three times the amount of damages that the
  state of Florida has sustained because of Lilly's actions, plus a civil penalty of not less than
  \$5,000 and not more than \$10,000 for each violation of FLA. STAT. ANN. §68.082(2)(a)(1);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to FLA. STAT. ANN. §68.085(1)-(2) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT VI.

## VIOLATION OF HAW. REV. STAT. §§661-21 to 661-29

- 95. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 96. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Hawaii in violation of HAW. REV. STAT. §661-21(a)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 97. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Hawaii's state funded Medicaid health care program false or fraudulent claims for payment in violation of HAW. REV. STAT. §661-21(a)(1).
- 98. Hawaii's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 99. The Hawaii State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of Hawaii's false claim provisions that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that the state of Hawaii has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of HAW. REV. STAT. §661-21(a)(1);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to HAW. REV. STAT. §661-27(a) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT VII.

## <u>VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION</u> <u>ACT, 740 ILL. COMP. STAT. 175/1-8</u>

- 100. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 101. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Illinois in violation of 740 ILL. COMP. STAT. 175/3(a)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 102. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Illinois' state funded Medicaid health care program false or fraudulent claims for payment in violation of 740 ILL. COMP. STAT. 175/3(a)(1).
- 103. Illinois' State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 104. The Illinois State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of the Illinois

Whistleblower Reward and Protection Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to three times the amount of damages that the state of Illinois

has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of 740 ILL. COMP. STAT. 175/3(a)(1);

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to 740 ILL. COMP. STAT. 175/4(d)(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT VIII.

## <u>VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS</u> INTEGRITY LAW, LA. REV. STAT. ANN. §§46:437.1-440.3

- 105. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 106. From at least January, 2003 continuing through April, 2009, Lilly, in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Louisiana in violation of LA. REV. STAT. ANN. §46:438.3(A) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 107. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta and Strattera causing to present to California's state funded Medicare Health Program false, fraudulent claims for payment in violation of LA. REV. STAT. ANN. §46:438.3(A).

- 108. The state of Louisiana's Medicaid program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 109. The state of Louisiana's Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiff demands judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Louisiana Medical Assistance Programs Integrity Law that this Court enter judgment in Plaintiff's favor and against Lilly a civil fine in an amount not to exceed three times the amount of damages that the state of Louisiana has sustained because of Lilly actions, plus payment of interest on the amount of the civil fine, plus a civil penalty of not more than \$10,000 for each violation of LA. REV. STAT. ANN. §46:438.3(A);
- b. that Relator, as Qui Tam Plaintiff, be awarded the maximum amount allowed pursuant to LA. REV. STAT. ANN. §46:438.4(A) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT IX.

## VIOLATION OF MASS. GEN. LAWS. CH. 12, §5A-50

- 110. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 111. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the

submission of false or fraudulent claims to be paid or approved by the Commonwealth of Massachusetts in violation of MASS. GEN. LAWS. CH. 12, §5B(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 112. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Massachusetts' state funded Medicaid health care program false or fraudulent claims for payment in violation of MASS. GEN. LAWS. CH. 12, §5B(1).
- 113. Massachusetts' Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 114. The Massachusetts Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of Massachusetts' false claim provisions that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to three times the amount of damages, including consequential damages, that the Commonwealth of Massachusetts has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of MASS. GEN. LAWS. CH. 12, §5B(1);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to MASS. GEN. LAWS. CH. 12, §5F(1)-(3) and/or any other applicable provision of law;

- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT X.

## VIOLATION OF NEV. REV. STAT. § 357.010-.250

- 115. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 116. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Nevada in violation of NEV. REV. STAT. § 357.014(1)(a) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 117. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Nevada's state funded Medicaid health care program false or fraudulent claims for payment in violation of NEV. REV. STAT. § 357.014(1)(a)).
- 118. Nevada's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 119. The Nevada State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of Nevada's false claim provisions that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to three times the amount of damages that the state of Nevada has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of NEV. REV. STAT. § 357.014(1)(a);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to NEV. REV. STAT. § 357.210(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relators have such other and further relief that this Court deems just and proper.

#### COUNT XI.

## <u>VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE</u> ANN. §§71-5-181 TO -185

- 120. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 121. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Tennessee in violation of TENN. CODE ANN. §71-5-182(a)(1)(A) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 122. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in

the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Tennessee's state funded Medicaid health care program false or fraudulent claims for payment in violation of TENN. CODE ANN. §71-5-182(a)(1)(A).

- 123. Tennessee's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 124. The Tennessee State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Tennessee Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that the state of Tennessee has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of TENN. CODE ANN. §71-5-182(a)(1)(A);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to TENN. CODE ANN. §71-5-183(c)(1) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XII.

## VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION STATUTE, TEX. HUM. RES. CODE ANN. §§ 36.001-.132

- 125. Relators repeat and reallege paragraphs 1-71 of this Complaint.
- 126. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Texas by causing false or fraudulent claims to be paid or approved by the state of Texas in violation of TEX. HUM. RES. CODE ANN. §36.002(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 127. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Texas' state funded Medicaid health care program false or fraudulent claims for payment in violation of TEX. HUM. RES. CODE ANN. §36.002(1).
- 128. Texas' State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 129. The Texas State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of the Texas Medicaid

Fraud Prevention Statute that this Court enter judgment in Plaintiffs' favor and against Lilly in

an amount equal to two times the amount of damages that the state of Texas has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of TEX. HUM. RES. CODE ANN. §36.002(1) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than \$1,000 and not more than \$10,000 for each violation of TEX. HUM. RES. CODE ANN. §36.002(1) that does not result in injury to a person;

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to TEX. HUM. RES. CODE ANN. §36.110 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

## COUNT XIII.

## <u>VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA. CODE</u> <u>ANN. §§ 8.01-216.1 – 216.19</u>

- 130. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 131. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the Commonwealth of Virginia in violation of VA. CODE ANN. § 8.01-216.3(A)(1) through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 132. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Virginia's state funded Medicaid health care program false or fraudulent claims for payment in violation of VA. CODE ANN. § 8.01-216.3(A)(1).
- 133. Virginia's Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 134. The Virginia Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Virginia Fraud Against Taxpayers Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that the Commonwealth of Virginia has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of VA. CODE ANN. §§ 8.01-216.3(A)(1);
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to VA. CODE ANN. § 8.01–216.7(A) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT XIV.

## VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT, GA. CODE ANN. § 49-4-168 – 49-4-168.6

- 135. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 136. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Georgia in violation of GA. CODE ANN. § 49-4-168.1 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 137. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Georgia's state funded Medicaid health care program false or fraudulent claims for payment in violation of GA. CODE ANN. § 49-4-168.1.
- 138. Georgia's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 139. The Georgia State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Georgia False Medicaid Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that Georgia has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of GA. CODE ANN. § 49-4-168.1;
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to GA. CODE ANN. § 49-4-168.2(i) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

### COUNT XV.

## <u>VIOLATION OF THE INDIANA STATE FALSE CLAIMS AND WHISTLEBLOWERS</u> PROTECTION ACT, IND. CODE ANN. § 5-11-5.5-1 - 5-11-5.5-18

- 140. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 141. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Indiana in violation of IND. CODE ANN. § 5-11-5.5-2 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 142. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Indiana's state funded Medicaid health care program false or fraudulent claims for payment in violation of IND. CODE ANN. § 5-11-5.5-2.
- 143. Indiana's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 144. The Indiana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Indiana State False Claims and Whistleblower Protection Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that Indiana has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 each violation of IND. CODE ANN. § 5-11-5.5-2;
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XVI.

## <u>VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT, MICH. COMP</u> LAWS § 400.601- 400.613

- 145. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 146. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Michigan in violation of MICH. COMP LAWS § 400.603, 606 and 607 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 147. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Michigan's state funded Medicaid health care program false or fraudulent claims for payment in violation of MICH. COMP LAWS § 400.603, 606 and 607.
- 148. Michigan's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 149. The Michigan State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of the Michigan State

Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in
an amount equal to three times the amount of damages that Michigan has sustained because of

Lilly's actions, plus a civil penalty equal to the full amount Lilly unjustly received as a result of its unlawful conduct for violating MICH. COMP LAWS § 400.603, 606 and 607;

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to MICH. COMP LAWS § 400.610a and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XVII.

# VIOLATION OF THE MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. § 17-8-401 – 17-8-412

- 150. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 151. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Montana in violation of MONT. CODE ANN. § 17-8-401 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 152. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Montana's state funded Medicaid health care program false or fraudulent claims for payment in violation of MONT. CODE ANN. § 17-8-401.

- 153. Montana's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 154. The Montana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Montana False

  Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount

  equal to not less than two times and not more than three times the amount of damages that

  Montana has sustained because of Lilly's actions, plus a civil penalty of not more than \$10,000

  for each violation of MONT. CODE ANN. § 17-8-401.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XVIII.

# VIOLATION OF THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS ACT, N.H. REV. STAT. ANN. § 167:58 - 167:61-b

155. Relator repeats and realleges paragraphs 1-71 of this Complaint.

- 156. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of New Hampshire in violation of N.H. REV. STAT. ANN. § 167:61-b through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 157. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to New Hampshire's state funded Medicaid health care program false or fraudulent claims for payment in violation of N.H. REV. STAT. ANN. § 167:61-b.
- 158. New Hampshire's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 159. The New Hampshire State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of the New Hampshire

Fraud and False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly
in an amount equal to not less than two times and not more than three times the amount of
damages that New Hampshire has sustained because of Lilly's actions, plus a civil penalty of not
less than \$5,000 and not more than \$10,000 for each violation of N.H. REV. STAT. ANN. §
167:61-b.

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.H. REV. STAT. ANN. § 167:61-e and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XIX.

# VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT, N.M. STAT. ANN. § 27-14-1 – 27-14-15

- 160. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 161. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of New Mexico in violation of N.M. STAT. ANN. § 27-14-4 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 162. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to New Mexico's state funded Medicaid health care program false or fraudulent claims for payment in violation of N.M. STAT. ANN. § 27-14-4.

- 163. New Mexico's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 164. The New Mexico State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the New Mexico

  Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in
  an amount equal to three times the amount of damages that New Mexico has sustained because
  of Lilly's and the co-conspirators' actions for violation of N.M. STAT. ANN. § 27-14-4.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.M. STAT. ANN. § 27-14-9 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XX.

# VIOLATION OF THE NEW YORK FALSE CLAIMS ACT, N.Y. STATE FIN. LAW § 187-194

- 165. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 166. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of New York in

violation of N.Y. STATE FIN. LAW § 189 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.

- 167. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to New York's state funded Medicaid Health Care Program false or fraudulent claims for payment in violation of N.Y. STATE FIN. LAW § 189.
- 168. New York's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 169. The New York State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the New York False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that New York has sustained because of Lilly's and the co-conspirators' actions, plus a civil penalty of not less than \$6,000 and not more than \$12,000 for each violation of for violation of N.Y. STATE FIN. LAW § 189.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.Y. STATE FIN. LAW § 190(6) and/or any other applicable provision of law;

- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XXI.

## VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT N.J. STAT. § 2A:32C-1 -17

- 170. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 171. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of New Jersey in violation of N.J. STAT. § 2A:32C-1 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 172. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to New Jersey's state funded Medicaid health care program false or fraudulent claims for payment in violation of N.J. STAT. § 2A:32C-1.
- 173. New Jersey's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 174. The New Jersey State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the New Jersey False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to not less than two times and not more than three times the amount of damages that New Jersey has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of N.J. STAT. § 2A:32C-1.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to N.J. STAT. § 2A:32C-7 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XXII.

# VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT 63 OKL. ST. § 5053-5053.7

- 175. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 176. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Oklahoma in violation of 63 Okl. St. § 5053.1 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 177. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in

the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Oklahoma's state funded Medicaid health care program false or fraudulent claims for payment in violation of 63 Okl. St. § 5053.1.

- 178. Oklahoma's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 179. The Oklahoma State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of the Oklahoma Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount equal to three times the amount of damages that Oklahoma has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000, if not already imposed by the Federal False Claims Act for the same or prior action, for each violation of for violation of 63 Okl. St. § 5053.1.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to 63 Okl. St. § 5053.1.4 and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XXIII.

# VIOLATION OF RHODE ISLAND'S STATE FALSE CLAIMS ACT R.I. GEN. LAWS § 9-1.1-1 - 9-1.1-8

- 180. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 181. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed, caused the submission of false or fraudulent claims to be paid or approved by the state of Rhode Island in violation of R.I. Gen. Laws § 9-1.1-1 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 182. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present to Rhode Island's state funded Medicaid health care program false or fraudulent claims for payment in violation of R.I. Gen. Laws § 9-1.1-1.
- 183. Rhode Island's State Medicaid Program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay Medicaid reimbursement that it would not otherwise have paid.
- 184. The Rhode Island State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

a. that by reason of the aforementioned violations of Rhode Island's State

False Claims Act that this Court enter judgment in Plaintiffs' favor and against Lilly in an

amount equal to three times the amount of damages that Rhode Island has sustained because of

Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000, for each violation of for violation of R.I. Gen. Laws § 9-1.1-1.

- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;
- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

#### COUNT XXIV.

# VIOLATION OF WIS. STAT. § 20.931 FOR FALSE CLAIMS FOR MEDICAL ASSISTANCE

- 185. Relator repeats and realleges paragraphs 1-71 of this Complaint.
- 186. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information it conveyed caused the submission of false or fraudulent claims to be paid or approved by the state of Wisconsin in violation of Wis. Stat. § 20.931 through its off-label promotion of the drugs Zyprexa, Symbyax, Cymbalta and Strattera.
- 187. From at least January, 2003 continuing through April, 2009, Lilly in reckless disregard or deliberate ignorance of the truth or falsity of the information conveyed, engaged in the practice of the off-label marketing of the drugs Zyprexa, Symbyax, Cymbalta, and Strattera causing to present Wisconsin's state funded medical assistance program false or fraudulent claims for payment in violation of Wis. Stat. § 20.931.

- 188. Wisconsin's state medical assistance program was unaware of the falsity of Lilly's records, statements and claims and as a result thereby has paid and continues to pay medical reimbursement that it would not otherwise have paid.
- 189. The Wisconsin medical assistance program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against Lilly as follows:

- a. that by reason of the aforementioned violations of Wis. Stat. § 20.931 for False Claims for Medical Assistance that this Court enter judgment in Plaintiffs' favor and against Lilly in an amount not less than two times and not more than three times the amount of damages that Wisconsin has sustained because of Lilly's actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000, for each violation of for violation of Wis. Stat. § 20.931.
- b. that Relator, as qui tam plaintiff, be awarded the maximum amount allowed pursuant to and/or any other applicable provision of law;

- c. that Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and
- d. that Plaintiff and Relator have such other and further relief that this Court deems just and proper.

Respectfully submitted,

DUANE MORRIS LLP

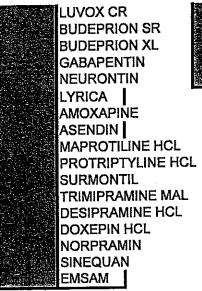
Michael M. Mustokoff (Atty. I.D. No. 15674) Mark Lipowicz (Atty. I.D. No. 20716) Teresa N. Cavenagh (Atty. I.D. No. 43845) 30 South 17<sup>th</sup> Street Philadelphia, PA 19103 (215) 979-1000

Attorneys for Plaintiffs

Dated: April 30, 2009\_

Exhibit A

Market	<b>श</b> ्वतार्थ		<b>शिल्हियां</b>	Butter (C)	1200100
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	ZOLOFT		SYMBYAX		ADDERALL
	PAROXETINE HCL		ZYPREXA INTRAMUS		DEXEDRINE
	PAXIL		LITHANE		METHYLPHENIDATE
	LUVOX		LITHIUM CARB		RITALIN
	EFFEXOR	9.50.2	LITHOBID		RITALIN-SR
	EFFEXOR XR		LITHONATE		CYLERT
	NEFAZODONE HCL		LITHOTABS		DEXEDRINE
	SERZONE		DEPAKOTE		METADATE ER
	WELLBUTRIN		DEPAKOTE ER		METADATE CD
	ANAFRANIL		DEPAKOTE SPRINKL		CONCERTA
	CLOMIPRAMINE HCL	7.5-1	CHLORPROMAZINE !		DEXTROAMPHETAMI
	AMITRIPTYLINE HCL		EQUETRO		ADDERALL XR
	ELAVIL		ESKALITH		AMPHETAMINE SALT
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	IMIPRAMINE PAM		FLUPHENAZINE DEC		DEXMETHYLPHEN H
	TOFRANIL		FLUPHENAZINE HCL		FOCALIN
	TOFRANIL-PM		LOXAPINE		FOCALIN XR
	AVENTYL		LOXITANE		METHAMPHETAMINE
	NORTRIPTYLINE HC		LOXITANE C		PEMOLINE
	PAMELOR		MELLARIL		METHYLIN ER
	DESYREL		MELLARIL-S	,	RITALIN LA
	TRAZODONE HCL		MOBAN		DEXTROSTAT
	VIVACTIL		NAVANE		VYVANSE
	MIRTAZAPINE		PERMITIL		DAYTRANA
	REMERON		PERPHENAZINE		
	REMERON SOLTAB		PROLIXIN		
2.12	WELLBUTRIN		PROLIXIN DECANOA		
	WELLBUTRIN SR		PROLIXIN ENANTHA	.1⊑	
	CELEXA		SERENTIL		
	CITALOPRAM HBR		STELAZINE		•
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	LEXAPRO		RISPERDAL M-TAB		
	ENDEP		RISPERIDONE		
	LUDIOMIL		SEROQUEL		
	WELLBUTRIN XL		GEODON		,
	PEXEVA		CLOZAPINE		
	SERTRALINE HCL		CLOZARIL		
	VENLAFAXINE HCL		ABILIFY		
	PRISTIQ		INVEGA		
National States					



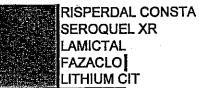


Exhibit B

# EXHIBIT B

# SEALED PER COURT ORDER

**Exhibit C** 



The brand strategy for Symbyax, with bipolar depression, remains focused on expanding use in the primary care setting and maintaining current prescribers in the psychiatry and account settings. The message objectives are first to partner with customers to improve the recognition and diagnosis of bipolar depression in their depressed patient population. Then, when customers recognize bipolar depression, position Symbyax as an appropriate treatment option because of the powerful antidepressant effect that has demonstrated the potential to significantly improve symptoms as early as week one. When discussing Symbyax, it is important to balance treatment considerations with potential efficacy benefits to meet customer needs.

### **Target Patient**

Bipolar Depression

## Symbyax Core Message Elements

- Symbyax is a powerful antidepressant for bipolar depression.
  - o Provides an enhanced effect on neurotransmitters important in the treatment of depression.
  - Improves symptoms as early as week one.
  - Offers clinically significant remission rates.

## **Customer Targeting**

Lilly Neuroscience will continue to target current prescribers to maintain or grow sales with Symbyax. NovaQuest PCP will expand use of Symbyax in primary care by messaging Symbyax in a P2 position with all Cymbalta targets. In October, it was recommended that NovaQuest utilize a targeted customer approach to achieve sales growth. The following two customer types should be targeted for incremental customer engagement plan activities:

- Expand the use of Symbyax with current prescribers by advancing the comfort with recognition and diagnosis of bipolar depression in their depressed patient population.
- Target a group of 10 Symbyax CATS target physicians that currently do not consider bipolar depression in their depressed patient population. Advance their comfort in recognizing bipolar depression and gain clinical experience with Symbyax.

Exhibit D

## Key Changes From Previous Sales Aid

You'll be happy to know that not much has changed since October. We have heard from many of you that the new Child 24-hour data and discontinuation data have been compelling information for your physicians. For March 2009, you will notice that we have strengthened Strattera's enduring efficacy story by enhancing these data as well as other areas of the IVA. These additions do not change the strategy or message, but should improve your interactions with your physicians.

The following includes all key changes in your March '09 sales materials:

- Patient Profiles: The ADHD patient profiles at the beginning of your child/adolescent and young adult/adult slides and tabs have been updated. The new profiles include more specific ADHD symptoms which outline unique patient needs.
- Enduring Efficacy Animation: We enhanced the child/adolescent and young adult/adult "enduring efficacy" data in the IVA by adding animation to bring it to life. Now you can more easily communicate the value that enduring efficacy provides to patients with ADHD.
- Maintenance Data: Information on the maintenance treatment of Strattera was first introduced in the November Psych IVA. This data has now been expanded to include not only mean time to relapse, but also percent of patients who relapsed.
- Enhanced Dosing Information: Several examples of quantifiable goals have been added to the child/adolescent and adult "Optimizing Treatment" slides and tabs.
- IVA Functionality: The IVA functionality has now been updated to allow you click on a graph and expand its view.
- Enduring Efficacy for Paper Sales Aid: The child/adolescent "Enduring Efficacy" tab in the paper sales aid has been updated to a text format. This will allow for an easier discussion around the key points of the data presented on this page. See the "enduringefficacy" section in "Areas of Concern" (AOCs) at the end of the Implementation Guide for further clarification around the child/adolescent "enduring efficacy" data.
- New Reprint: We now have a new reprint available on the discontinuation data presented in your sales aid. The Wernicke reprint will be available in your IVA as well as printed for dissemination to your customers.

Exhibit E

### Sales Director/Manager Facilitator's Guide

- I. Introduction/Overview
  - a. Elaine's voicemail ensure that everyone received the voicemail and understands the context of the call
  - b. As a result of new data analysis, the focus of our promotion and core sales pieces have changed
- II. Implementation Guides
  - a. Imp Guide Overview
    - Once the overview is complete and everyone understands the purpose of the call, begin to transition into the Implementation Guide
    - ii. This IVA DOES NOT have any of the painful physical symptom data, it is important to highlight this at the beginning
    - iii. The IVA provides a story around relapse, which will be our promotional focus in the short term
      - 1. For the Psych/Account TVA there is also a GAD abbreviated message
      - 2. Novaquest and Cardio do not have IVAs they will receive a four page sales aid via mail on Thursday. This message is an abbreviated version of the relapse message

#### III. Programming Changes

- We have pro-actively decided to make changes to the current Cymbalta promotional slide kits
- b. The Cymbalta MDD promotional slide kits (core, emotional, and painful physical symptoms) are no longer available for use
- c. The GAD kit is the only non-pain related kit available for programming
- d. Representatives should contact speakers for which they have responsibility (see below for further clarification)
- e. As of Monday, April 6, any MDD program (core, emotional, or painful physical symptoms) will automatically be converted by LLB into a GAD program
- f. Additionally, speakers will receive a revised GAD kit on the 6th
- g. The representatives will then have the opportunity to change the program to DPNP, Fibromyalgia, or cancel the program. Until further notice, only GAD, Fibromyalgia, and DPNP programs may be scheduled
- h. These limitations are temporary and speaker kit revision is a top priority
- IV. Representative Action Items
  - a. Among the files for download is the representative action communication which provides an action plan for the representatives in addition to a destruction notice
  - b. The key points/timelines are as follows:
    - i. After the call, the representative should download the new IVA, delete the existing IVA, read the implementation guide, and read the sales representative action document

Exhibit F

I was referred to you because I feel so sad and anxious, and at work I can't seem to get anything done

Sad Loss of interest Anxious Crying Vague aches Cymbalta is indicated for the acute and maintenance treatment of major depressive disorder (MDD).

#### Important Safety Information

- Antidepressants increased the risk of suicidal thinking and behavior (suicidality)
  in short-term studies in children, adolescents, and young adults with major depressive
  disorder (MDD) and other psychiatric disorders.
- Patients of all ages started on therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- · Cymbalta is not approved for use in pediatric patients.

See Important Safety Information, including Boxed Warning, on back page. Full Prescribing Information provided.





### Opening dialogue to share with customers

"Doctor, with Cymbalta you've come to expect transparency and proactive communication on topics important to your practice and your patients. As a result, I want to make you aware that we are in the midst of a proactive assessment of the Cymbalta data used in promotion, to ensure it meets Lilly's commitment to clinical and regulatory standards.

As a result, you will see a change in the patient type I will be describing today, as one of the areas under consideration revolves around Cymbalta's data in painful physical symptoms. While this process is occurring, I will be sharing data in a patient with major depression who is at risk of relapse.

Over the coming months, I will share with you any changes or additions to our core data for MDD and GAD, so that you can continue to make informed decisions as to how to incorporate Cymbalta into your practice."

Exhibit G

## Brand Strategy

In October 2008, we introduced the new Strattera "Stay by their side" campaign as an appeal to physicians who, in market research, told us that they worry about their patients when their symptoms of ADHD are uncontrolled (not just during the daytime hours). While the tag line "Stay by their side" should not be used as a verbatim with physicians, it intuitively expresses Strattera's benefit: <a href="enduring efficacy">enduring efficacy</a> that gives patients with ADHD the coverage they need in different settings throughout the day.

In 2009, the Strattera strategy remains the same:

- Remind HCPs about the efficacy and safety of Strattera in treating ADHD symptoms...Why they should
  use Strattera
- 2. Inform HCPs on How to use Strattera (dosing, adequate trial duration, side effects, expectations)

#### **Target Patient**

The ADHD patient who is vulnerable to symptoms of impulsivity and inattention in different settings throughout the day and evening.

### Core Message Elements

- Patients with ADHD are vulnerable to symptoms such as impulsivity and inattention at different times and in different settings
- Strattera provides enduing efficacy in ADHD
- Understanding how to appropriately dose and set expectations is key to success with Strattera

### Key Takeaways

1. HCPs need to be aware of the efficacy and safety of Strattera in treating ADHD symptoms

When HCPs think of Strattera, they must remember that Strattera treats symptoms of ADHD. In particular, they must be reminded of the efficacy of Strattera in treating the inattentive and impulsive symptoms associated with ADHD. These are often the symptoms that physicians want to treat for a duration longer than just the work or school day.

2. We need to inform HCPs of multiple strategies to help their patients achieve better outcomes with Strattera. These are the "How to's".

We need to continue being open and transparent with HCPs regarding response rates, dosing, gradual onset of action, and potential adverse events in order to help HCPs and their patients achieve a better overall experience with Strattera. Patients' knowledge of what to expect with Strattera is critical in their achieving a more meaningful experience with the product. We need to take responsibility for doing more to help patients use Strattera successfully.

Exhibit H

# CERTIFICATE OF SERVICE

I, Teresa N. Cavenagh, hereby certify that a true and correct copy of the foregoing Complaint has been served this 1st day of May, 2009, by certified mail, return receipt requested unless otherwise noted upon the following:

### SERVICE LIST

Eric H. Holder, Jr., Attorney General United States Department of Justice 950 Pennsylvania Avenue, N.W. Washington, DC 20430-0001	Laurie Magid, United States Attorney c/o Virginia Gibson, Chief, Civil Division United States Attorney's Office 615 Chestnut Street, Suite 1250 Philadelphia, PA 19106-4476 (Via Hand Delivery)
Office of the Attorney General, California Jerry Brown 1300 I Street, Suite 1740 Sacramento, California 95814	Office of the Attorney General, Hawaii Mark J. Bennett 425 Queen Street Honolulu, Hawaii 96813
Office of the Attorney General Medicaid Fraud Control Unit Michael L. Parrish, Director 333 Queen Street, 10 <sup>th</sup> Floor Honolulu, Hawaii 96813	Office of the Attorney General Medicaid Fraud Control Unit W. Rick Copeland, Director 6330 Hwy. 290 East Suite 250 Austin, Texas 78723
Delaware Office of the Attorney General Joseph R. Biden, III Carvel State Office Building 820 N. French Street Wilmington, DE 19801	Linda Singer Office of the Attorney General for the District of Columbia Attention: Stephane Latour Chief, Civil Enforcement Section 441 4 <sup>th</sup> Street, NW, Suite 450 North Washington, DC 20001

Office of the Attorney General, Tennessee Robert E. Cooper, Jr. P. O. Box 20207 Nashville, Tennessee 37202-0207	Office of the Attorney General, Texas Greg Abbott Attorney General Capitol Station P. O. Box 12548 Austin, Texas 78711-2548
Office of the Attorney General, Illinois Lisa Madigan James R. Thompson Center 100 W. Randolph Street Chicago, Illinois 60601	Office of the Inspector General District of Columbia Susan Kennedy, Director Medicaid Fraud Control Unit 717 14 <sup>th</sup> Street NW, 5 <sup>th</sup> Floor Washington, DC 20005
Office of the Attorney General, California Mark Geiger, Director Bureau of Medi-Cal Fraud 1425 River Park Drive, Suite 300 Sacramento, California 95815	Office of the Attorney General, Virginia Bill Mims Randal L. Clouse, Director Medicaid Fraud Control Unit 900 E. Main Street, 5 <sup>th</sup> Floor Richmond, Virginia 23219
Office of the Attorney General, Massachusetts Martha Coakley Christopher Walsh, Director Medicaid Fraud Control Unit 1 Ashburton Place Boston, Massachusetts 02108	Office of Attorney General State of Florida Bill McCollum The Capitol PL-01 Tallahassee, FL 32399-1050
Office of Attorney General, Nevada Catherine Cortez Masto 100 North Carson Street Carson City, Nevada 89701-4717	Office of the Attorney General, New Hampshire Kelly A. Ayotte 33 Capitol Street Concord, NH 03301
Carlotta R. Hivoral Deputy Attorney General Bureau of Medi-Cal Fraud and Elder Abuse 1455 Frazee Road, Suite 315 San Diego, CA 92108-4304	Office of the Attorney General, New York Andrew M. Cuomo The Capitol Albany, NY 12224-0341

Office of the Attorney General Medicaid Fraud Control Unit of Florida David Lewis, Director 107 West Gaines Street The Capitol – PL-01 Tallahassee, FL 32399-1050	Office of the Attorney General, Montana Steve Bullock Justice Building 215 N. Sanders Helena, MT 59620-1401
Charles Richards Director, MFCU Georgia State Healthcare Fraud Control Unit 2100 East Exchange Place Building 1, Suite 200 Tucker, GA 30084	Office of the Attorney General, Georgia Thurbert E. Baker 40 Capitol Square, SW Atlanta, GA 30334
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Suite 409

Washington, DC 2009

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## UNITED STATES DISTRICT COURT

Address of Plaintiff: John Doe  Address of Defendant: Lilly Corporate Center, Indianapolis, Indiana	
See of Against Incident or Transaction: California and across the United States	
(Use Reverse Side For Additi	
Ooes this civil action involve a nongovernmental corporate party with any parent corporation and a (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ. P. 7.1 (a))	ny publicly held corporation owning 10% or more of its stock?  Yes No
Ooes this case involve multidistrict litigation possibilities?	Yes 🔲 No 🔀
THE CAR IN AMY.	
RELATED CASE, IF ANT:  Case Number: Judge Date T	Cerminated:
Civil cases are deemed related when yes is answered to any of the following questions:	
1. Is this case related to property included in an earlier numbered suit pending or within one year	Yes 🔛 No 🔀
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior	suit pending or within one year previously terminated
action in this court?	Yes 🗌 No 🖾
3. Does this case involve the validity or infringement of a patent already in suit or any earlier	numbered case pending or within one year previously
terminated action in this court?	Yes 🗌 No 🔀
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights of	case filed by the same individual?
4. Is this case a second of Successive limited corpus, section 27	Yes 🗌 No 🔀
CIVIL: (Place ✓ in ONE CATEGORY ONLY)  A. Federal Question Cases:	B. Diversity Jurisdiction Cases:
Indemnity Contract, Marine Contract, and All Other Contracts	1. Insurance Contract and Other Contracts
2.  FELA	2. Airplane Personal Injury
3.  Jones Act-Personal Injury	3. Assault, Defamation
4. Antitrust	4. Marine Personal Injury
5. Patent	<ol> <li>Motor Vehicle Personal Injury</li> </ol>
6. Labor-Management Relations	6. Other Personal Injury (Please specify)
7. Civil Rights	7. Products Liability
8. Habeas Corpus	8. Products Liability — Asbestos
9. Securities Act(s) Cases	9. All other Diversity Cases
10. Social Security Review Cases	(Please specify)
11. All other Federal Question Cases (Please specify)	
False Claims Act 31 U.S.C. § 3729  ARBITRATION CERTI  (Check appropriate Cate	gory)
I, Michael M. Mustokoff , counsel of record do hereby certif	iy:
Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge a exceed the sum of \$150,000.00 exclusive of interest and costs;	and belief, the damages recoverable in this even ablion out
Relief other than monetary damages is sought.	
DATE: May 1, 2009 Michael M. Mustokoff Attorney-at-Law	15674 Attorney l.D.#
NOTE: A trial de novo will be a trial by jury only if there ha	as been compliance with F.R.C.P. 38.
I certify that, to my knowledge, the within case is not related to any case now pending or except as noted above.	within one year previously terminated action in this court
DATE: May 1, 2009 Melace h. Me	estiles 15674

CIV. 609 (6/08)

# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

### CASE MANAGEMENT TRACK DESIGNATION FORM

**CIVIL ACTION** 

United States Ex Rel. John Doo	• •		
<b>v.</b> .	:	210	
Eli Lilly & Company	: :	NO.	
plaintiff shall complete a case filing the complaint and serve side of this form.) In the evidesignation, that defendant shall other part which that defendant believes	Management Track Designation a copy on all defendants. (See ent that a defendant does not all, with its first appearance, sies, a case management track	eduction Plan of this court, courd from Form in all civil cases at the § 1:03 of the plan set forth on the agree with the plaintiff regarding submit to the clerk of court and submit to the clerk of	time of reverse ng said erve on
•	ought under 28 U.S.C. §2241 th		( )
	questing review of a decision of a plaintiff Social Security Be		( )
(c) Arbitration – Cases require	ed to be designated for arbitrati	on under Local Civil Rule 53.2.	( )
(d) Asbestos – Cases involvin exposure to asbestos.	g claims for personal injury or	property damage from	( )
commonly referred to as c	ses that do not fall into tracks (omplex and that need special of the of this form for a detailed exp	r intense management by	(X)
(f) Standard Management – C	Cases that do not fall into any or	ne of the other tracks.	( )
May 1, 2009  Date	Michael M. Mustokoff Attorney-at-law	Plaintiff Attorney for	<u>.</u>
215.979.1810 Telephone	215.689-3607 FAX Number	mmustokoff@duanemorris.co E-Mail Address	om

(Civ. 660) 10/02

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